

# **Purdue Quarterly Report to the Board April 21, 2010**

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## MARKETING & SALES

Assure 2010 sales and market share targets are met or exceeded. The 2010 ex-factory sales budget is \$3,244.3 mm (a 5% increase over 2009 actual).

Meet or exceed total prescriber call targets of 540,000 with OxyContin in 100% primary position, Ryzolt in second position on at least 90% of calls, and Senokot/Colace in third position on at least 70% of calls. Compliance with all relevant policies, government law and regulation will be closely monitored.

### Sales

The Sales and Marketing Department will contribute to profitability by ensuring that 2010 sales budget is met or exceeded.

Gross Sales Budget: \$3,244.3MM

Net Sales Budget: \$2,623.6MM

### **Results:**

2010	Actual		Budget		Prior Year	
(\$MM)	Gross Sales	Net Sales	Gross Sales	Net Sales	Gross Sales	Net Sales
Q1	693.2	544.0	663.9	529.5	618.8	505.9
Q2			833.0	673.4	693.1	550.8
Q3			965.5	778.3	733.1	626.5
Q4			781.9	642.4	967.3	756.9
Total	693.2	544.0	3,244.3	2,623.6	3,012.2	2,440.0

Actual Q1 2010 net sales were higher than budget and prior year by 2.6% and 7.5% respectively. See separate Q1 2010 financial statement package for more detail.

### Operating Budget

The department will operate within the total 2010 S&P budget of \$226 million which is 8.6% of total net sales of \$2.6 billion.

### **Results:**

2010	Actual		Budget		Prior Year	
	\$MM	% net sales	\$MM	% net sales	\$MM	% net sales
Q1	45.8	8.4%	54.3	10.3%	42.0	8.3%
Q2			58.8	8.7%	42.9	7.8%
Q3			54.4	7.0%	43.5	6.9%
Q4			58.6	9.1%	42.4	5.6%
Total			226.0	8.6%	170.9	7.0%

### **Business Unit Performance**

Each Branded Business Unit will strive to maintain established contribution on net sales for each promoted brand.

#### **OxyContin Product Contribution:**

2010	Actual		Budget		Prior Year	
	\$MM	% net sales	\$MM	% net sales	\$MM	% net sales
Q1	462.9	89.8%	444.6	88.7%	431.5	90.0%
Q2			588.1	91.0%	488.7	92.9%
Q3			673.4	89.8%	565.5	93.7%
Q4			533.7	87.0%	677.3	93.6%
Total	462.9	89.8%	2,239.9	89.2%	2,163.0	92.7%

#### **Ryzolt Product Contribution:**

2010	Actual		Budget		Prior Year	
	\$MM	% net sales	\$MM	% net sales	\$MM	% net sales
Q1	(6.6)	-	(7.3)	-	(0.0)	-
Q2			(7.8)	-	(13.4)	-
Q3			(6.5)	-	(14.9)	-
Q4			(6.5)	-	(14.9)	-
Total	(6.6)	-252.7%	(28.2)	-	(43.3)	-

#### **Laxative Product Contribution:**

2010	Actual		Budget		Prior Year	
	\$MM	% net sales	\$MM	% net sales	\$MM	% net sales
Q1	5.6	53.8%	5.2	40.8%	5.3	40.6%
Q2			5.1	39.4%	2.0	22.6%
Q3			5.4	41.4%	0.3	5.1%
Q4			5.2	40.0%	5.6	35.6%
Total	5.6	53.8%	20.9	40.4%	13.3	29.7%

In order to maximize sales force effectiveness, we will meet or exceed total prescriber call targets of 540,000 annually for 2010.

- OxyContin will be in the primary position on 100% of calls.
- Ryzolt will be in second presentation position in at least 90% of calls
- Senokot/Colace will be in third position in at least 70% of all calls.

**Result:** Overall, thru the end of the 1<sup>st</sup> quarter 2010, our sales calls are 4.9% above target. OxyContin and Ryzolt are slightly shy of their call position targets at 97% and 89% respectively, while we exceeded our call goals for laxatives coming in at 73%.

2010	Call Goal	Calls Made	Difference	% to Goal	OxyContin Primary % of all	Ryzolt Secondary % of all	Senokot/Colace Third % of all
Q1	127,376	133,561	6,185	105%	97%	89%	73%
Q2	142,657						
Q3	144,414						
Q4	125,553						
Total	540,000	133,561	6,185	25%	97%	89%	73%

Source: Phoenix

In order to increase productivity, we will improve the daily call average from 6.8 prescribers each day in 2009 to 7.5 in 2010, thereby lowering the current cost per call from \$219 to \$201. This has the potential to create efficiency of \$10+ million and increase sales revenue.

**Quarterly Result:** The sales force is falling short on prescriber calls by -0.5 calls per day per representative.

2010	Daily Average Call Target	Daily Call Average Actual	Prior Year
Q1	7.5	7.0	6.7
Q2	7.5		6.8
Q3	7.5		6.9
Q4	7.5		6.9

Source: Report Gallery - Metrics Report (weeks of 1/2 - 4/2/2010)

OxyContin Market Share objective for Long Acting Single Entity Opioids is 32%

Quarterly Result: 2.0 million Long Acting Single Entity Opioid prescriptions were written in January 2010, a decrease of 7.5% from the previous month. Branded OxyContin TRx volume decreased 12.2% from the previous month. Total Oxycodone ER share is above goal at 32.1%

		Jan 2010 TRx	Feb 2010 TRx	Share of LA SEO Market Feb 2010	Growth Over Previous Month Feb 2010	Growth Over 3 months Feb 2010	Growth Over 6 Months Feb 2010	Growth Over 12 Months Feb 2010
<b>Molecule</b>	<b>Total LA SEO Market</b>	<b>2,089,892</b>	<b>2,001,842</b>	<b>100.0%</b>	<b>-4.2%</b>	<b>-0.2%</b>	<b>-1.4%</b>	<b>-1.0%</b>
<b>OXYCODONE</b>	<b>OxyContin</b>	541,884	499,787	25.0%	-7.8%	-10.7%	7.9%	7.6%
	<b>Generic OER</b>	130,003	139,727	7.0%	7.5%	98.1%	-34.8%	-34.3%
	<b>Total Oxycodone-ER</b>	671,887	639,514	31.9%	-4.8%	-0.6%	-1.2%	-3.3%
<b>FENTANYL PATCH</b>	<b>Duragesic</b>	27,003	24,657	1.2%	-8.7%	-16.9%	-13.6%	-17.6%
	<b>Generic Fentanyl Patch</b>	506,348	485,082	24.2%	-4.2%	-0.4%	-4.1%	-8.1%
	<b>Total Fentanyl</b>	533,351	509,739	25.5%	-4.4%	-1.4%	-4.7%	-8.8%
<b>MORPHINE</b>	<b>MS-Contin</b>	2,427	2,291	0.1%	-5.6%	-9.1%	-16.6%	-17.6%
	<b>Avinza</b>	36,133	32,938	1.6%	-8.8%	-12.7%	-16.2%	-13.8%
	<b>Kadian</b>	48,043	45,845	2.3%	-4.6%	-6.1%	-10.2%	-16.3%
	<b>Generic 2X/Day Morphine</b>	389,669	376,545	18.8%	-3.4%	2.2%	3.1%	12.8%
	<b>Embeda</b>	7,327	8,719	0.4%	19.0%	192.5%	-	-
<b>OXYMORPHONE</b>	<b>Opana-ER</b>	55,825	54,572	2.7%	-2.2%	4.3%	10.4%	42.6%
<b>METHADONE</b>	<b>Methadone</b>	345,230	331,679	16.6%	-3.9%	0.3%	-1.1%	3.2%

Source: IMS NPA (February 2010 data month)

## MANUFACTURING & SUPPLY CHAIN

Assure compliance with all FDA, DEA, OSHA and EPA laws and regulations. Transition the manufacture of OxyContin to the new formulation. Ensure all product development targets are met. Maintain manufacturing and distribution budgetary provisions for 2010.

### Wilson

Wilson manufactured 217 batches in Q1-10 (100% schedule adherence). These batches were comprised of 128 OxyContin batches, 65 MS Contin batches, and 24 development/validation batches (2 ONU, 5 MSER, 8 ORF low ABUK, and 9 Oxy IR).

Listed below are additional in process Wilson projects that impact Supply Chain Management for the 1<sup>st</sup> quarter:

- Work is progressing on the Warehouse/Vault expansion. All walls, floors, and roofing are complete. The project is maintaining the approved budget, and completion is expected by the end of the 2<sup>nd</sup> quarter of 2010.
- The batch scale up for 80mg ORF is complete. The final report is being written and should be in place in time to support the initial ORF launch quantities. This will improve efficiencies in Operations and the QC lab areas.
- The advanced planning optimization project is moving into the design phase. An SAP consultant specializing in APO implementation has been contracted to assist with the project.
- One of the packaging teams has been allocated to a weekend shift (Fri – Sun) to make packaging line 2 available for RFID upgrade activity. The weekend shift will be in place for ~9 weeks to allow RFID upgrades to be completed on both packaging lines.

#### **Production Facility (Status) – Totowa, NJ**

- No commercial production was done in the Totowa facility during the 1<sup>th</sup> quarter.
- PF Labs continues to serve as the trans-shipping point for Dilaudid into Canada and Australia.
- PF Labs vaults and warehouse continue to be used for overflow from the Wilson site.

#### **DEA Manufacturing/Procurement Quota Status (for commercial products only)**

**Oxycodone:** The 2010 Commercial Quota granted by DEA for Oxycodone was 20,074 kgs. This represents roughly 75% of 2010 OxyContin production and sales requirements.

**Morphine:** The 2010 Commercial Quota granted by DEA for Morphine was 4,663 kgs. This supports the small amount of Branded MS Contin sales and roughly 55% of the increasing Watson sales for MSAG.

**Hydromorphone:** The 2010 Quota for Hydromorphone is 25 kgs for Product Development.

#### **Pharmaceutical Technology**

##### **ONU (Targin)**

- Project underway in Wilson; one experimental batch has been manufactured using each process (one multi-strand, and one chilled roller/single-strand).

##### **ORF**

- 80mg scale-up validation report being finalized (all data now received).
- Completed manufacture of batches to support the Noramco low ABUK oxycodone qualification.
- Started manufacture of 3 batches to support clinical study 3001.
- 40/60 scale-up validation campaign scheduled to begin upon approval (approx. 4/5/2010)
- 10 ft3 V-blender modifications for containment completed on Totowa blender. Process Hazard Analysis conducted.



#### **MSER (aNDA Product)**

- Validation batches completed

#### **OxyIR (Rhodes Pharma)**

- Validation batch manufacture completed. Awaiting BU/CU/dissolution results before beginning launch build (estimated start date 04/19/10).

#### **Import / Export**

Activities continue with the collaborative efforts of the Miami office, Wilson, and Supply Chain Operations group in Totowa handling the labeling transition to color shifting inks. Completion of the transition is anticipated for the first semester of 2011.

#### **Inventory Management/Inventory Accuracy**

The Wilson Cycle Count inventory accuracy in Q1 result is 100%, and the Louisville Inventory Accuracy result is 99.9% - excellent performance in both sites.

#### **Third Party Contract Manufacturing & Packaging**

- Anderson Packaging -On-going projects are Slow-Mag pouches, commercial ONF launch and BuTrans. Anderson has provided a quote to package Dronabinol which is under review.
- Avema Pharma Solutions - Supply Chain continues to work with Avema as a potential supply source for Senokot, Senokot-S, Peri-Colace and Slow-Mag. Avema is currently working on providing us with tablet samples for Senokot, Senokot-S, and Peri-Colace matched for color, shape, and size. Tablets will be available early April. The Slow-Mag project is still under discussion at Avema and a revised proposal is pending.
- G & W - A decision out of the CPPC meeting was rendered Tuesday, March 9th to discontinue Colace Suppositories.
- Hospira - Sales of Dilaudid injectables continue to exceed forecast. Hospira advised Purdue of a capacity constraint on their vial and lyophilizer. These constraints will impact our ability to maintain target days supply of 4 months at these increased sales levels.
- Labopharm - Current projections on Ryzolt inventory obsolescence due to unrealized demand (stemming from initial launch quantities) is estimated at \$651,123.
- LTS - Supply chain to import BuTrans placebo patches to execute a shipping study. Other launch readiness activities are also underway including; API (Bup) sourcing strategy from Tasmanian Alkaloids, API Stockpiling, Capacity Expansion in Andernach.
- Purdue (Canada) - Due to the regulatory issues around approving natural source Senokot and Senokot S from Canada, all product manufactured remains on hold in Louisville. Activities are



underway in an attempt to resolve the regulatory issues for the natural source senna products, as well as to use Purdue Canada as a source of calcium sennaside products.

- Sharp – Sharp continues to package the OxyContin HUD SKU's as we plan for the transition to ORF in the third quarter. Sharp will also be poised to package the Rhodes Pharma Oxy IR stability lots in May.
- Time Cap Labs –Time Cap Labs is on target to deliver Senokot and Senokot-S HUDs by end-April. Senokot-S 30's with IRC is on target for mid-May delivery.

#### **Supply Management – Procurement Highlights:**

Supplier Performance for Q1 was 94% Right the First Time for raw materials and packaging components. There were 83 receipts and 5 supplier issues. All issues were resolved with no impact on production/packaging.

- Developing a second source for polyethylene oxide
- Pursuing PCI Synthesis as custom manufacturer and finalized both a CDA and MSA with the supplier; also, established a CDA with Novasep, another potential source
- Received proposal from PCI Synthesis which is currently under cross functional review at Purdue
- Qualification of Noramco Low ABUK Oxycodone for ORF
- Batches were produced and activities are on schedule in accordance with the project timeline

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## **QUALITY**

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Sustain company compliance with all laws and regulations related to cGxP from drug development through commercialization. Support the accurate and timely release of approved quality product. Assure integrity and qualification of all new product development, technology transfer and regulatory filings.

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#### **Sustained Compliance**

- Each of the PPLP sites continues to have a favorable compliance status resulting in no significant observations from regulatory inspections. All sites remain in a state of FDA inspection readiness.
  1. A biennial FDA general GMP inspection is expected at Purdue Pharmaceuticals, as well as pre/post-approval inspections for Wilson manufactured ORF and Rhodes Pharmaceuticals Oxy IR. Additionally, they are anticipating an inspection by ANVISA (Brazil Health Authority for Latin America).
  2. Two FDA inspections (BUP Sponsor and biennial Pharmacovigilance) are anticipated in 2010 for the Stamford facility.

3. Rhodes Technologies is anticipating a biennial FDA general GMP inspection which may include pre-approval readiness inspections for Hydrocodone Bitartrate API, PPLP ONF or Rhodes Pharmaceuticals Oxy IR.
- Commercial product complaint metrics show that the process is in control, and remains compliant with no significant change in the number of complaints received.
  - Time-Cap Labs was again inspected by the FDA in March 2010, and they are expecting several 483 observations. At this time, no observations are known to involve Purdue product.
  - Wellspring (supplier of Colace liquid and packager of Peri-Colace blisters and Colace capsules) alerted Purdue in December 2009 to an out of specification stability result for Colace liquid. All product lots were put on hold and an investigation was initiated. The unknown impurity was identified as benzophenone, which was introduced by manufacturers of inks and varnishes, used by the packaging material manufacturers that supply Wellspring.
  - Filing for Hydrocodone Bitartrate has been completed.

### **Manufacturing Support**

- Integration of SOPs across the Wilson and Totowa facilities is progressing, and being managed by GxP Training to facilitate the backup capability of Totowa.
- Wilson achieved 100% on-time release and shipment of product for 1Q2010. Additionally, all release cycle time goals were met. All investigations and complaints were closed within the 30-day time period as required by procedure unless an interim report was issued.
- G&W (Colace suppositories supplier) has refused to accommodate audits in order to reserve time to address 483 observations issued in their last FDA inspection and open warning letter. According to Supplier Quality Assurance's Standard Operating Procedures, given their non compliance with a request for a routine audit, G&W will be dropped from the approved supplier list.

### **Support for New Products**

- The proactive preparation throughout 2009/2010 for an FDA Sponsor inspection for BuTrans led by the Stamford Quality Council continues to be a key activity supported by multiple departments across PPLP.
  1. Regulatory Affairs was contacted by FDA on April 6, 2010, indicating that a Sponsor Inspection will begin on April 12, 2010, focusing on the BUP3015 and BUP3024 pivotal studies.
  2. Four BuTrans clinical sites were FDA inspected in December 2009 and January 2010 with no significant issues identified.
- Analytical methods were successfully transferred to Wilson for the testing of ONU (Oxycodone / Naloxone Tablets). Napp Pharmaceutical, in collaboration with Wilson and Cranbury, is in the process of finalizing the transfer report.
- Support was provided for two FDA submissions by Rhodes Pharmaceuticals – the ANDA for Oxycodone / APAP Tablets and the response to FDA questions for Oxycodone HCl IR Tablets.

### **Process Excellence**

- QC laboratory efficiencies were gained through successful completion of qualification studies permitting reduced testing for the remainder of the year for Noramco Oxycodone HCl.
- Validation studies were successfully completed for the Tablet Process Workstation (TPW3). The validation report has been written and is in review. Upon completion of comparison studies, the TPW3 will permit unattended automated content uniformity testing of ORF.

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## **RESEARCH & DEVELOPMENT**

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The overarching objectives for US R&D can be considered in three categories. The first and highest priority is to secure final approval for reformulated OxyContin® and BuTrans®. The second is to secure agreement with FDA on development and approval requirements for Targin®, and following this, to either initiate work on these requirements or begin efforts to compile and submit the NDA. The third objective is to advance the remainder of the existing pipeline (HYD, POA and TRPV-1).

- Reformulated OxyContin®
- BuTrans® (BTSD)
- Targin® (ONU)
- Hydrocodone QD (HYD)
- Peripheral Opioid Agonist (POA)
- TRPV-1 (VND)

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### **Reformulated OxyContin (OTR/ORF)**

- Approval of Reformulated OxyContin (NDA 22-272) received on April 5, 2010.
- Approval includes acceptance of Purdue's Risk Evaluation and Mitigation Strategy (REMS)
- Post-marketing commitments include an oral chewing PK study (ongoing) and a post-marketing epidemiology study to determine the impact, if any, of the reformulated product on various patient and non-patient outcomes of interest.

### **BuTrans™**

- PDUFA date remains June 30, 2010
- NDA prosecution activities including REMS development, label negotiation and FDA inspection of the Stamford facility (clinical study documentation) are ongoing in support of expected approval on PDUFA date.
- Additional strength program (15, 25, 30 and 40mg) to be initiated upon approval of 5, 10 and 20mg strengths.

#### Targin® (ONU)

- IND submitted February 26, 2010, IND in effect
- Briefing package containing Purdue's proposed NDA submission content and strategy submitted to FDA on March 30, 2010 – NDA submission plan to initiate upon receipt of response from FDA (expected within 45 days).

#### Hydrocodone QD (HYD)

- Formulation under development; 2<sup>nd</sup> round of PEO-based variants undergo pharmacokinetic testing in 2Q10. If formulation target is achieved, candidate will be selected for continued development in 3Q10.

#### Peripheral Opioid Agonist (POA V113741)

- Program on "Partial Clinical Hold" as of Jan 27<sup>th</sup> 2010.
- A plan is being developed to address the current dosing limitation and also to develop definitive plans for Proof of Concept (POC) studies.

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#### **PLANNING & OUTSOURCE MANAGEMENT**

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Relative to the 2010 Scorecard savings target, POM is accruing \$1,124,351 in Rebates (PRA – other rebates pending), \$63,333 in negotiated savings, and \$14,400 in POM savings)

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#### **DISCOVERY RESEARCH**

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#### Exploratory Formulations Polycaprolactone

- Purdue Polycaprolactone formulation patent has published.

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## COMPLIANCE

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Assure compliance with Purdue's Corporate Integrity Agreement (CIA) and all Federal and State laws and regulations, as well as the PhRMA Code. Conduct risk assessments and audit and monitor business operations. Respond as required to all inquiries and conduct investigations of Company operations when appropriate. Assure that all ethics and compliance training requirements are met.

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### Corporate Integrity Agreement

By letter dated April 1<sup>st</sup>, Purdue's OIG Monitor confirmed that upon its review of Purdue's Second Annual Report (submitted September 2009) and supplemental information provided in response to OIG's request, Purdue was in compliance with the terms of its Corporate Integrity Agreement during the second reporting period.

Purdue has a five year CIA that ends July 30, 2012, subject to normal post-annual report review. Our next major milestone is an IRO review this summer followed by our third Annual Report this September.

### Freedom of Information Act (FOIA) Request to OIG for Disclosure of Purdue CIA Annual Reports

By letter dated March 9<sup>th</sup>, OIG advised they had received a FOIA request from Public Citizen for disclosure of copies of Purdue's annual reports filed with OIG together with other materials. Relying on FOIA statutory exemptions, HHS regulations, and case law, Purdue submitted a response to OIG on March 31<sup>st</sup> stating the position that the majority of such materials must not be released since the request seeks "proprietary and confidential information," including "trade secrets and commercial or financial information obtained from a person and privileged or confidential," recognized grounds for exemption from disclosure.

### Healthcare Reform Legislation

The passage of Healthcare reform legislation has significant compliance implications as the Board has heard previously. Specifically, all pharmaceutical and device manufacturers will be required to track annual spending on individual physicians and "teaching hospitals" beginning January 2012, and submit annual reports each year beginning March 31, 2013. The information will be posted on a website to be made available to the public. In addition, reporting of samples will be required on an annual basis, but will not be posted on a public website. The Corporate Compliance group is leading a project that will enable the company to aggregate and report such spending information on a company-wide basis, in compliance with the requirements.

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## BUSINESS DEVELOPMENT

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Licensing and business development work will support the diversification of the product portfolio in the analgesic, CNS, GI and other relevant categories.

Execute against the following objectives:

1. Comprehensive Analgesic Plan
  - Seek Board approval for 2 term sheets
  - Seek Board approval to enter into 1 contract negotiation
2. Related Core Therapeutic Area – insomnia, GI, CNS
  - Seek Board approval for 1 term sheet
  - Seek Board approval to enter into 1 contract negotiation
3. Final Product Transaction Agreement
  - Complete 1 Rx product transaction

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### High Priority Projects Under Review Jan – March 2010

#### Progenics Pharmaceuticals

- Relistor® (methylnaltrexone SC injection) approved in 50 countries for advanced illness opioid-induced constipation; oral under development opioid-induced constipation in the setting of chronic pain. Oral patents were filed in March 2010 based on the Wyeth inventions/data. A pivotal phase III program would be needed for approval in the U.S. for the broad oral market opportunity. To be competitive, the oral would need to be approved prior to Q1 2014. We are in the process of validating the clinical development plan and understanding the deal terms for this late-stage opportunity.

#### Theravance

- TD-5108 is a 5HT-4 agonist for chronic constipation (CIC); an initial sales forecast has just been generated; a comprehensive phase III chronic illness development plan is being reviewed; TD-1211 is a peripheral Mu receptor antagonist for OIC in phase I development.

#### Clinical Data

- Vilazodone is a SSRI/5HT1a for major depressive disorder; the NDA was submitted at the end of March. We have dropped out of the deal negotiations based on unrealistically high expectations of Clinical Data.

#### Pacira Pharmaceuticals

- Exparel™ (depobupivacaine injection) for post op pain; DD ongoing on this phase III opportunity

## Somaxon Pharmaceuticals

- Silenor® (doxepin 3mg and 6mg) approved by the FDA March 17, 2010 for the treatment of insomnia characterized by sleep maintenance difficulty; we have just entered into confidential discussions with the company around a marketing partnership to launch the approved drug in September.

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## **FINANCE / INFORMATION TECHNOLOGY**

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Assure 2010 sales, profitability, efficiency, cash flow, compliance and pipeline objectives are supported by proactive, future-focused and meaningful financial analysis. Assure that Purdue's financial reporting and forecasting are informative and give the reader transparency into business results. Assure robust systems of financial and financial reporting internal controls are in place.

Assure that Purdue has cost effective systems that ensure and enable compliance that give Purdue competitive advantage.

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### **Financial Performance**

- Purdue closed Q1 2010 with sales, expenses, cash, distributions, working capital and other indicators at or better than budget as follows:

(\$mm)	Q1 2010		Variance % FAV/(ADV) vs. Budget	Q1 2009 Actual
	<u>Actual</u>	<u>Budget</u>		
Net Branded Revenue	544	529	2.8	505
Operating Expenses	133	155	14.0	125
Net Profit before Tax	368	348	5.7	320
Cash – Unrestricted	506	471	7.4	494
Accounts Receivable Days	32.1	35.0	9.0	32.6

- The sales favorability vs. budget is primarily due to higher OxyContin wholesaler inventory (+ \$95.7 mm) offset by higher generic utilization (-\$33.1mm), lower demand/seasonality in the OER market (-\$35.3 mm) and higher rebates (-\$12.4mm). The inventory and generic variances are temporary. The demand and rebate variance could impact full year sales – we will know more over the next few months.
- The Operating Expense favorability vs. budget is due to program delays in R&D (-\$7.7 mm), timing of S&P spend (-\$7.0mm) and other, including several million of savings, which will likely be permanent.



### **Finance Department**

- As reported at recent Board meetings Purdue is obligated under the McGinty patent license from Abbott to have \$100mm in product liability insurance. As commercial insurance is not available for OxyContin our most likely approach to meet this obligation would have been to post a \$100mm letter of credit with an insurer or with Abbott. We recently concluded a successful renegotiation of this obligation with Abbott under which the insurance obligation is deferred as long as Purdue's net worth is \$500mm or higher (net worth at March 31, 2010 was \$732mm). The financial reporting obligation is limited to a certificate from Ernst & Young stating that Purdue's Net Worth is \$500 mm or higher.
- Our Internal Audit Function (IAF) and Executive Audit Committee report the following:
  1. Inventory cycle counts were performed in Wilson, Totowa and Louisville (third party). The cycle counts revealed no inventory shortages. The cycle counts revealed a number of opportunities to improve control, which have all been implemented.
  2. Twenty individual, material accounting positions were taken by Purdue in preparing its 2009 financial statements. The Committee and Ernst & Young agreed with the positions recommended.
  3. The Committee periodically asks management to confirm that all prior audit recommendations have been implemented. Generally, all prior audit recommendations have been or are in the process of being implemented. One exception is the review approval and distribution of promotional or educational materials. The recommendations in this area should be implemented by a new headcount approved in Regulatory Affairs, and by a new work flow IT system within the next few months.

### **Real Estate**

- Summer Street – Our goal is to reduce the cost of early termination of the lease by \$5mm through subletting the space. Purdue is working with the property owner (Benenson) and a potential tenant (GE Asset Management) on a lease proposal that, if closed, would achieve the \$5mm savings goal.
- On Stamford Realty – Our goal is to reduce the cost of carrying vacant space by subletting space. Purdue is working on a lease proposal to Louis Dryfus Highbridge Energy LLC that, if closed, would earn Purdue \$1.4mm per year and have Purdue assume ownership of UBS' \$13mm generator at no cost.

### **Procurement**

- Our Procurement team, working with Purdue business leaders reported \$6.0mm in savings in the first quarter against a full year target of \$26mm. These savings are primarily negotiated savings vs. what Purdue paid for some items in prior years on prior contracts.

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## EXTERNAL AFFAIRS

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Build support for appropriate pain care through policy development and implementation. Take appropriate action on external threats to optimal pain care. Promote Purdue's reputation in academic, community and scientific venues. Address proposed legislation and regulation that may affect the Company and its products. Develop and support innovative programs that safeguard public health and address abuse and diversion of prescription medication.

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### **Build support for appropriate pain care through policy development and implementation.**

- Successfully passed a state prescription monitoring program bill in collaboration with the Attorney General in South Dakota. This brings the total number of states with enacted legislation for PMPs to 41.
- Seek PCF support for influencing FDA through stakeholders efforts to gain a "class" REMS so that all Schedule II and III opioids are treated equally and ensure an even playing field with ongoing patient access without burdening the healthcare system.
- Worked to defeat patent settlement legislative efforts in Congress that would have prohibited or restricted settlements between brand and generic companies.

### **Take appropriate action on external threats to optimal pain care.**

- Important state activity in Washington where legislation was passed that would establish mandatory guidelines for the treatment of pain and sets a prescribing threshold above which a consult with a pain specialist must occur in order to continue treatment. This action is concerning since the state already has interagency guidelines for State Medical Directors (AMDG) where above 80 total mg of oxycodone/day requires a pain consult however there are only 15 pain management consultants identified by AMDG. We believe that this has the potential to be a model that will be pushed out to other states. The guidelines take effect in July 2011.
- Work with Pain Care Forum stakeholders to defend optimal pain care. The Health Care Reform law contains the provisions of the National Pain Policy Act, which was created by the stakeholders of the PCF.

### **Promote Purdue's reputation in academic, community and scientific venues.**

- Developed and disseminated information and education on appropriate pain care and policy via an e-newsletter and In the Face of Pain® website that is published through the Healthcare Alliance Development group.
- A multi-departmental Corporate Key Opinion Leader (KOL) project has been initiated to collect and manage the relationships with key opinion leaders who may support appropriate use of pain medications and/or generally advocate for access to appropriate pain care.
- Sponsorship of "Choices for Connecticut", a year-long public policy awareness program produced by The Business Council of Fairfield County, provided a televised Gubernatorial Debate and a Legislative Leadership breakfast with Purdue prominently displayed as the sponsor of the program.

- Collaborated with celebrity spokesperson Lee Woodruff to promote the Caregiver Cornerstones campaign and the Disabled American Veterans Winter Games. This outreach garnered more than 50 media stories, including Good Morning America Health, Better TV and a cover story in *Pain Pathways* magazine. Partnering with the American Academy of Pain Management, almost 30 radio interviews featuring Partners Against Pain. In the first quarter were secured. More than 136 million people have been exposed to Purdue's unbranded pain management messages via the media.

**Address proposed legislation and regulation that may affect the Company and its products.**

- Senator Bono Mack introduced a bill HR 4956 To direct the Commissioner of Food and Drugs to modify the approval of any drug containing controlled-release oxycodone hydrochloride to limit such approval to use for the relief of severe-only instead of moderate-to-severe pain, and for other purposes. Working with Pain Care Forum stakeholders we will attempt to gain friendly members of Congress to defend against movement of this legislation

**Develop and support innovative programs that safeguard public health and address abuse and diversion of prescription medication.**

- A partnership with US Conference of Mayors to raise the public awareness of the danger of abusing prescription medication and safe storage has been initiated that includes the production of public service announcements.
- National Association of State Controlled Substance Authorities (NASCSA) announced the availability of grants for state prescription drug monitoring programs made available through financial support of Purdue Pharma L.P.
- Community Partnerships activities:
  1. Developed and launched pilot Medicine Cabinet public service campaign in Tampa with TV advertising and print materials.
- Conducted proactive media relations to promote RxPatrol and the Law Enforcement Liaison & Education program. Achieved positive delivery of Purdue's anti-diversion/anti-abuse by garnering more than 250 stories to an estimated 6.4 million readers/views.

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## HUMAN RESOURCES

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Design, communicate and implement rewards programs that drive alignment and achievement of corporate and individual performance objectives. Staff positions with highly capable talent and assure employee engagement and retention. Develop employees through relevant and meaningful programs and assignments while providing for future succession requirements. Assure program and management compliance with all regulatory and legal requirements.

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### Staffing

- Dr. Margaretta Nyilas, Executive Medical Director, joined Purdue on March 1<sup>st</sup>, reporting to Dr. Craig Landau, Vice President & Chief Medical Officer.
- Marty Nealy has accepted an offer of the position of Executive Director, Plant Manager-Wilson, reporting to David Lundie, Vice President, Manufacturing & Supply Chain. It is anticipated that he will begin employment May 2, 2010.

### Performance Partnership, Individual Development Plan & Bonus Planning

- Human Resources implemented Performance Partnership (appraisal program), Individual Development Planning, the 2009 and 2010 bonus planning process, and 2010 merit increase planning by assisting managers with colleague performance calibration and decision making to support retention of high performing colleagues and appropriate recognition and reward for individual contribution.
  1. The Company portion of 2009 Annual Bonus awards was paid at 113.6% reflecting performance compared to objectives included in the 2009 Business Success Scorecard.
  2. 2010 merit increases were made at the 2010 budget level of 3% of salaries. Additionally, salary reviews were completed to provide appropriate market and internal equity increases where warranted by employee performance.
  3. Completed the Purdue 2010 Business Success Scorecard
  4. HR is providing support to the Rhodes HR Committee and Board. Most recently HR facilitated the development of 2010 Business Scorecards and 2010 Individual Objectives for Rhodes executives and colleagues.

### Development & Training

- HR facilitated a new Rotational Development Program for colleagues in Security, Quality and Manufacturing. The program was introduced to provide opportunities for high performing colleagues for further career development, and to broaden career experience and skills. A survey is being developed to solicit feedback on the program effectiveness.
- Overall findings of the Field Sales District Manager's 360° Feedback Survey, designed to address evolving demands on Purdue's District Managers, reveal high competency in compliance, communication and leadership. Business management and talent development scores are considered improvement opportunities, although the scores were highly rated.

- Human Resources, Law and the Sales organization developed action plans to address diversity representation in the Sales Force and to provide development opportunities and diversity awareness.

### Compliance

- 2010 Affirmative Action Plans have been completed for all companies.
- A Company-wide Fraud and Abuse Control Information System (FACIS) Level 3 review has been conducted for all employees of PPLP and U.S. Associated Companies on February 25, 2010. All current employees are "sanction free".
- The Totowa facility successfully completed a DEA background check audit for Line Contractors in March without any observations.

### EHS

The Process Hazard Analyses of ORF has been completed at Totowa and of Dilaudid in Wilson. Exhaustive analyses of manufacturing process, material handling and engineering controls were reviewed for safety and environmental hazards, with recommendations developed and tracked for completion before the process can run at each facility.

### Facilities

- Refurbishment of the 6th floor of One Stamford Forum is underway with an estimated completion date of May 31. Starting on June 1, we will relocate the remaining 160 colleagues now located at Summer Street to the 6th floor. As we have pursued creative reuse of the UBS fit-out, the capital project will be completed substantially below budget. While we have made a careful effort to accommodate the needs of our Finance and IT group, the modified open floor plan is a diversion from our customary office fit-out and we anticipate a longer than usual settling in period as our colleagues adjust to the new open plan. Choyce Peterson is representing our attempt to sublet our leased premises at 1600 Summer Street; while overall activity has been only light to moderate, our space is still in the running as a single user progresses toward making a final selection. We are working with UBS to sublet the 2nd and 3rd floors of OSF and are currently in late stage negotiations with a premium tenant.

### Latin American Business

- Total "to-the-market" net sales through March reached \$4.0M. This represents 128% of the year to date budget, and 19% over the same period in 2009. Total "in- the-market" sales (Tecnofarma sales) through March reached \$3.1M, representing 95% of the year to date budget. Sales in Argentina, Brazil and Peru were well over our expectations, but Colombian sales were significantly below budget due to competition from another oxycodone sustained release product.
- Negotiations with Tecnofarma for renewal of the distribution agreement throughout most of Latin America continue. Progress is being made in improving some of the terms and conditions of our current contract, including provision for a small upfront payment on renewal, certain sales milestone payments, an order shortfall provision and other contract enhancements. We will be meeting later this month for further negotiations.
- We continue to explore possible partnership with additional firms for the Targin product. Two firms have indicated possible interest in marketing the product to date, Eli Lilly and Moksha8.

Jansen (J&J) was contacted earlier and indicated interest, but our European colleagues asked that we not work with them as doing so might compromise European Targin strategies and sales.

## Full-Time Turnover Projection

March YTD 2010

	Begin Count	End Count	Ave # EE's	Termina- tions	% Term EE's	Retired	Resigna- tions	% Resigned	Total T/O	YTD T/O Rate
S&P										
Sales	490	489	490	5	1.0%	0	4	0.8%	9	1.8%
Marketing	42	42	42	0	0.0%	0	0	0.0%	0	0.0%
Sales Support	23	25	24	0	0.0%	0	0	0.0%	0	0.0%
Field Ops, Support & Admin	12	14	13	0	0.0%	0	0	0.0%	0	0.0%
Total S&P	567	570	569	5	0.9%	0	4	0.7%	9	1.6%
% of X-FTE's				55.6%		0.0%	44.4%			
G&A										
Administrative Services	32	32	32	0	0.0%	0	0	0.0%	0	0.0%
Business Development	7	7	7	0	0.0%	0	0	0.0%	0	0.0%
Corporate Compliance	7	8	8	0	0.0%	0	0	0.0%	0	0.0%
EHS	5	5	5	0	0.0%	0	0	0.0%	0	0.0%
Executive	15	14	15	2	13.3%	0	0	0.0%	2	13.3%
External Affairs	15	15	15	0	0.0%	0	0	0.0%	0	0.0%
Finance	53	54	54	1	1.9%	0	0	0.0%	1	1.9%
General Counsel	52	52	52	0	0.0%	0	0	0.0%	0	0.0%
Human Resources	21	21	21	0	0.0%	0	0	0.0%	0	0.0%
IT	86	85	86	1	1.2%	0	0	0.0%	1	1.2%
Procurement	15	15	15	0	0.0%	0	0	0.0%	0	0.0%
QA	21	21	21	0	0.0%	0	0	0.0%	0	0.0%
Security	15	15	15	0	0.0%	0	0	0.0%	0	0.0%
Total G&A	344	344	344	4	1.2%	0	0	0.0%	4	1.2%
% of X-FTE's				100.0%		0.0%	0.0%			
IRD/US										
Discovery	47	48	48	0	0.0%	0	0	0.0%	0	0.0%
Drug Safety & Pharma	33	34	34	0	0.0%	0	0	0.0%	0	0.0%
Health Policy	40	40	40	0	0.0%	0	0	0.0%	0	0.0%
Medical Research	53	53	53	0	0.0%	0	2	3.8%	2	3.8%
Nonclinical & R&D	41	40	41	2	4.9%	0	0	0.0%	2	4.9%
Project Management	21	21	21	0	0.0%	0	0	0.0%	0	0.0%
Regulatory Affairs	18	18	18	0	0.0%	0	0	0.0%	0	0.0%
Total IRD/US	253	254	254	2	0.8%	0	2	0.8%	4	1.6%
% of X-FTE's				50.0%		0.0%	50.0%			
MFG/OPERATIONS										
PF Labs Salaried	22	22	22	0	0.0%	0	0	0.0%	0	0.0%
PPMD	58	58	58	0	0.0%	0	1	1.7%	1	1.7%
Wilson NC	182	180	181	2	1.1%	0	0	0.0%	2	1.1%
Total MFG/OPERATIONS	262	260	261	2	0.8%	0	1	0.4%	3	1.1%
% of X-FTE's				66.7%		0.0%	33.3%			
Rhodes Technologies	95	93	94	0	0.0%	0	1	1.1%	1	1.1%
Rhodes Pharma	39	0	20	0	0.0%	0	0	0.0%	0	0.0%
Total MFG/OPERATIONS	396	353	375	0	0.0%	0	1	0.3%	1	0.3%
				0.0%		0.0%	100.0%			
Total Miami	3	3	3	0	0.0%	0	0	0.0%	0	0.0%
% of X-FTE's				0.0%		0.0%	0.0%			
Grand Total	1,825	1,784	1,805	13	0.7%	0	8	0.4%	21	1.2%
% of X-FTE's				61.9%		0.0%	38.1%			